

**2004 FSIS
National Residue
Program**

**FOOD SAFETY AND
INSPECTION SERVICE**

**2004 FSIS
NATIONAL
RESIDUE PROGRAM**

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PREFACE

Welcome to the 2004 "Blue Book." This book presents the 2004 Food Safety and Inspection Service (FSIS) National Residue Program (NRP).

This text presents a comprehensive explanation of the process used to plan the NRP for 2004. In 1999, the NRP was modified to move towards a system of residue evaluation more consistent with modern risk assessment principles. The methodologies employed in the planning of the 2004 NRP, as described in this document, reflect these changes. Following the explanation of the planning process, this text provides a detailed description of the completed Domestic Monitoring Plan and Special Projects and Import Residue Plan for the 2004 FSIS NRP.

In addition to a description of the annual NRP, this Blue Book contains updated versions of four tables that our readers have found very useful: a list of the type and amounts of tissue collected for each analysis conducted in the FSIS NRP; a list of all established tolerances and action levels for drugs and food additives in food animal tissues; a list of all established tolerances and action levels for pesticides and environmental contaminants in food animal tissues; and a list that provides the performance characteristics and analytical methodologies of the FSIS Official Methods used in the NRP. These tables appear as Appendices I through IV, respectively, at the end of this publication.

The staff of the Residue Branch, Food Animal Sciences Division, Office of Public Health Science, FSIS, hope that you will find this *2004 National Residue Program* to be useful and informative. We would like to thank all of our predecessors for providing us with tables and information that they developed and that we continue to use.

CONTACTS AND COMMENTS

Questions about the FSIS NRP should be directed to the USDA-FSIS Zoonotic Diseases and Residue Surveillance Division, Residue Branch, 344 Aerospace Center, 1400 Independence Avenue, SW, Washington, DC 20250-3700, telephone (202) 690-6566, fax (202) 690-6565.

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Section 1

The 2004 FSIS National Residue Program

Introduction

An essential aspect of food safety in meat, poultry, and egg products is the control of residues that may result from the use of animal drugs and pesticides, or from incidents involving environmental contaminants. The United States has a complex residue control system, with rigorous processes for approval, sampling, testing, and enforcement. Three principal agencies are involved in the control of residues in meat, poultry, and egg products: the Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA), the Food and Drug Administration (FDA), and the Environmental Protection Agency (EPA). FDA and EPA establish tolerances (maximum permissible levels) for chemical residues in foods, and FSIS enforces these tolerances through its various residue control programs.

FDA establishes tolerances for veterinary drugs and food additives under the statutory authority of the Federal Food, Drug, and Cosmetic Act (FFDCA). These tolerances are published in Title 21 of the Code of Federal Regulations (CFR). EPA establishes tolerances for registered pesticides under the statutory authority of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and FFDCA, as modified by the Food Quality Protection Act (FQPA), which are published in 40 CFR. Action Levels for industrial chemicals (e.g., cancelled pesticides) and industrial chemicals (e.g., PCBs) are established by FDA or FSIS based on recommendations published by EPA in the Federal Register.

Under the Federal Meat Inspection Act (FMIA), the Poultry Products Inspection Act (PPIA), and the Egg Products Inspection Act (EPIA), FSIS acts to ensure that USDA-inspected meat, poultry and egg products do not contain illegal levels of chemical residues. The cornerstone of FSIS residue prevention activities is the FSIS National Residue Program (NRP), a multi-component analytical testing program for residues in domestic and imported meat, poultry, and egg products. The FSIS NRP, which has been in effect since 1967, provides a variety of sampling strategies to prevent violative residues from entering the food supply, and develops national data on the occurrence of chemical residues to support risk assessment, enforcement and educational activities. The range of chemical compounds evaluated for inclusion in the various NRP testing programs is comprehensive in scope. It includes approved and unapproved pharmaceutical drugs and pesticides known or suspected to be present in food animals in the U.S. and in countries exporting products to the U.S. It also includes any other xenobiotic or naturally occurring compounds that may appear in meat, poultry, and egg products and that may pose a potential human health hazard.

The NRP is designed to provide: (1) a structured process for identifying and evaluating compounds of concern by production class; (2) the capability to analyze for compounds of concern; (3) appropriate regulatory follow-up of reports of violative tissue residues; and (4) collection, statistical analysis, and reporting of the results of these activities.

When violative residues are detected in food-producing animals submitted for slaughter, FSIS notifies the producer and other parties involved in offering these animals for sale. Product found to contain violative levels of residues is considered adulterated and is subject to condemnation. If the product has been distributed into commerce, it may be subject to voluntary recall and/or other actions. In addition, FDA and cooperating state agencies may make on-site visits to these firms. Typically, an educational visit by the state is the first step in attempting to correct a residue problem. If the problem is not corrected, subsequent visits, made by FDA, could result in enforcement action, including prosecution. As of

September 5, 2001, FSIS will post, on its website (www.fsis.usda.gov), the names and addresses of parties that FDA has determined are responsible for more than one drug, pesticide or other chemical residue violation in a 12-month period. FSIS believes that this new policy will act as a more effective deterrent against the repeated sale of livestock or poultry containing violative levels of chemical residues, and enable the Agency to make better use of its residue testing resources.

An additional function of the FSIS NRP is to provide verification of residue control in Hazard Analysis and Critical Control Point (HACCP) systems. Under FMIA, and PPIA, the ultimate responsibility for ensuring that product is not adulterated when it enters commerce rests with the slaughter and processing establishments that produced the product. To define and formalize this responsibility, on July 25, 1996 USDA published the *Final Rule on Pathogen Reduction; Hazard Analysis and Critical Control Point Systems*. The principal focus of this rule is to reduce the incidence of foodborne illness associated with meat and poultry. Part 417 of the HACCP regulation requires meat and poultry establishments to develop and implement a system of preventive measures designed to ensure the safety of their products. In developing their HACCP plans, slaughter establishments must address all chemical, physical, and biological hazards that are reasonably likely to occur in the animals that enter their plants. Therefore, as part of the HACCP regulation, slaughter and production establishments are required to identify all chemical residue hazards that are reasonably likely to occur, and develop systems to guard against them. A vigilant chemical residue prevention program is essential to foster the prudent use of drugs and pesticides in animals that enter the human food supply. The requirement that slaughter establishments implement HACCP systems is a significant step in this evolutionary process.

The goals of the NRP can be summarized as follows:

- Enforce Federal laws and regulations;
- Maintain consumer confidence by ensuring that meat, poultry, and egg products are not adulterated;
- Act as a deterrent against the slaughter of adulterated animals and the processing of adulterated eggs;
- Identify violative product and prevent its entry into the food supply;
- Assess and communicate human exposure to chemical residues; and
- Provide verification of residue control in HACCP systems.

Section 2

The 2004 FSIS National Residue Program Components

Domestic Residue Sampling Program

The Food Safety and Inspection Service (FSIS) National Residue Program (NRP) provides a variety of sampling plans to verify and ensure that slaughter establishments are fulfilling their responsibilities under the Hazard Analysis and Critical Control Point (HACCP) regulation, and in accordance with Food and Drug Administration (FDA) and Environmental Protection Agency (EPA) regulations, to prevent the occurrence of violative residues. The residue data are collected in the NRP and the data are used to support risk assessment, enforcement, and educational activities. Residue data are entered into the FSIS Microbiological and Residue Computer Information System (MARCIS). Detailed information on violations is immediately transferred to the Residue Violation Information System (RVIS), which facilitates regulatory follow-up on violations and tracking of residue violators by both FSIS and FDA.

Components of the NRP for domestically produced products include the following:

- **Monitoring Plan**

The FSIS Monitoring Plan is designed to provide statistical information about the occurrence of violations. A violation occurs when a chemical residue is found in a production (food) animal or egg product and the residue is in excess of an established tolerance or action level. FSIS monitors for violations by collecting samples from food animals. Collected monitoring samples are sent directly to an FSIS laboratory. Monitoring plan data are obtained from sampling healthy food animals and normal egg products that have passed inspection. Neither the animal carcass nor the egg product is retained after sampling, and these products are permitted to enter the food supply. Food animals and egg products are sampled at one of the following four levels: 460; 300; 230; or 90 samples per year (see Section 4 for an explanation). If the test results indicate that there is a potential public health concern, product that has entered the food supply can be subjected to voluntary recall. The monitoring data are analyzed on an annual, national basis.¹

The compounds considered for monitoring have tolerances or action levels established by either FDA or EPA. Compounds are selected for Domestic Monitoring Plan using the formal selection procedures described in the publication “2002 FSIS National Residue Program” Chapters 4, 6, and 8.

Monitoring Plan data are used to indicate the prevalence and concentrations of residues, to evaluate residue trends, and to identify problems within the industry for which educational or other corrective efforts may be needed. Monitoring results can also be used to identify producers or other entities that market animals with violative concentrations of residues. The Monitoring Plan, therefore, not only gathers information, but also assists in deterring practices that lead to violative residues.

¹ Certain residues may be sampled for less than 12 months.

- **Surveillance**

Surveillance sampling is scheduled to investigate and control the occurrence of residue violations in slaughter classes or egg products that are suspect because of previous residue findings, information from the field, and information from FDA. Surveillance consists of random sampling designed to measure the extent of problems in suspect populations/products and to evaluate the impact of actions taken to reduce the occurrence of residues. In-plant testing procedures may be performed by the veterinarian-in-charge, or samples may be submitted to an FSIS laboratory for analysis. Depending upon the weight of evidence that led to the testing, product may be retained until test results indicate the appropriate regulatory disposition.

- **Exploratory Projects**

Exploratory Projects are conducted for a variety of reasons. Test results are not used to take regulatory action or to trigger follow-up action. Exploratory projects generally fall into one of the following categories:

1. Exploratory Projects study the occurrence of residues for which no residue limits have been established. There are many chemicals (e.g., trace metals, industrial chemicals, and mycotoxins) that may be inadvertently present in animals yet have not established residue limits. Their presence in edible tissues and the resulting need for residue limits to protect public health have not been established. FSIS may conduct studies to develop information on the frequency and concentration at which such residues occur.
2. Other projects may be designed for various purposes, such as evaluating new methods and approaches to monitoring, or supplementing the information used in considering a compound for monitoring.

- **Enforcement Testing**

FSIS Enforcement samples are collected from individual suspect animals. FSIS in-plant personnel select animals for testing based on herd history, and antemortem or postmortem findings. Enforcement testing is performed to detect individual animals with violative concentrations of residues. This testing is used as a tool to prevent carcasses with violative residues from entering the food supply. Enforcement testing is also used to follow up on producers and others who have marketed animals with violative concentrations of residues to determine if the non-compliance has been corrected, or to verify the performance of an establishment's Hazard Analysis and Critical Control Point (HACCP) system in controlling violative residues.

Samples collected under enforcement testing can either be tested in the plant using a rapid screening test, in which samples with positive test results are sent to the laboratory for confirmatory testing, or sent directly to the laboratory for testing. The carcass is retained pending the laboratory results. Carcasses found to contain violative concentrations of residues are considered adulterated and are condemned.

FSIS On-Site Rapid Screening Tests

FSIS currently employs the following on-site rapid screening tests:

1. Swab Test on Premises (STOP) was implemented in 1979 to detect the presence of antibiotic residues in kidney tissues. Originally developed for testing dairy cows, now it is approved for use in all species. While STOP is not designed to detect sulfonamides, it can register a positive at high concentrations. Additionally, producers will often use antibiotics in combination with sulfonamides. For these two reasons, the FSIS laboratory tests STOP positive samples for sulfonamides as well as antibiotics.
2. Fast Antimicrobial Screen Test (FAST) detects both antibiotic and sulfonamide drug residues in kidney tissues. At this time, it has been approved for use in bovines only. It has proved to be a suitable replacement for CAST and STOP in this species, as it is both quicker and more sensitive. FAST was implemented in bovine pilot plants in 1995 extended to approximately 50 of the largest cow and bob veal slaughtering plants in 1996, and is currently employed in all plants that slaughter cattle.
3. The Sulfa-On-Site Test (SOS) was implemented in 1988 to test swine urine for sulfonamide residues. SOS was used in many of the largest swine slaughtering facilities, but was cancelled in January 2004.

In summary, the Monitoring Plan is designed to obtain information for exposure assessment and to determine the prevalence of residue violations in the U.S. food supply. Monitoring samples are collected only from food animals and egg products that have passed USDA inspection and these products are permitted entry into the food supply. In contrast to the Monitoring Plan, enforcement testing is designed to prevent adulterated product from entering the food supply. Enforcement sampling targets suspect animals that have an abnormal or unhealthy appearance, show abnormal postmortem signs, or which are suspicious based on herd history. Under enforcement testing a carcass is retained pending laboratory results and if violative residue level is found, the carcass is considered adulterated and is condemned. Enforcement testing also occasionally includes samples from animals that have already been condemned by FSIS based on postmortem inspection.

In contrast to enforcement testing, which targets suspect animals, surveillance testing targets suspect populations. Carcasses selected for surveillance testing may or may not be retained pending the results of laboratory tests.

Contamination Response System

The Contamination Response System (CRS) is not a testing plan, but rather an emergency response management system for FSIS, FDA, and EPA. There are certain pesticides and environmental contaminants whose detection may suggest the occurrence of a potential risk to consumers. Detection of these residues immediately initiates a rapid follow-up investigation to characterize and address the residue problem. Actions taken may include investigation of any entity from the producer to the retailer and, if needed, withdrawal of the product from the market. This system is also triggered following the detection of banned veterinary drugs.

Import Residue Sampling Program

The Federal Meat Inspection Act (FMIA), Poultry Products Inspection Act (PPIA), and Egg Products Inspection Act (EPIA) require foreign countries that export meat, poultry, or egg products to the U.S. to establish and maintain inspection systems that are equivalent to those of the U.S. Countries must undergo a rigorous review process before they can become eligible to export meat, poultry and egg products to the U.S.

Residue control is a major feature of an inspection system that must be judged equivalent to the U.S. system before a country becomes eligible to export to the U.S. Foreign countries exporting to the U.S. are required to have protection from foodborne hazards equivalent to that of the U.S. These may include the following: random sampling of animals at slaughter; use of approved testing methods; testing appropriate target tissues, even though such tissue may not be exported to the U.S.; testing for compounds identified as potential contaminants of meat exported to the U.S.; and random sampling of eggs presented for processing.

After a foreign country is determined to have an equivalent system of inspection and becomes eligible to export product to the U.S., FSIS relies on the country's national inspection authorities to certify that establishments meet all applicable standards and are authorized to export to the U.S. FSIS performs periodic audits of the foreign inspection systems. The frequency and extent of audits depend on the country's performance history, including the results from previous plant reviews and product reinspection at the port-of-entry. If a country does not maintain an inspection system equivalent to the U.S. system, it is not permitted to export product to the U.S.

As a further check on the effectiveness of the foreign inspection system, FSIS randomly samples meat, poultry, and egg products for residues at the U.S. port-of-entry. Sampling at the port-of-entry is based on the Import Residue Plan, which is designed annually by FSIS. Components of FSIS import residue sampling include Monitoring, Increased Monitoring, Surveillance, and Exploratory Testing. These are described below:

- **Monitoring**

Import monitoring involves the sampling of specified raw or processed products to provide information about the occurrence of residue violations on an annual, international basis.

Monitoring information is obtained through a statistically based random selection of products that have passed inspection from the foreign country. The probability of detecting a violation varies positively with the number of samples analyzed and the true violation rate of the product being tested. The results are used to identify countries whose product contains violative concentrations of residues. When a violation is found in a product, the foreign country is subjected to increase testing until compliance is demonstrated. The product is not retained after the sample is taken.

- **Increased Monitoring**

Increased import monitoring occurs when FSIS finds a violation in a sample from a foreign country.

- **Surveillance**

Import surveillance occurs when FSIS suspects that product from a specific country may have violative concentrations of a residue. Surveillance is designed to measure the extent of problems, and to evaluate the impact of actions taken to reduce the occurrence of residues in imported products.

- **Exploratory Testing**

Import exploratory testing occurs when FSIS determines a need to study a specific product or compound that is being imported from one or more countries.

Residue sampling of meat and poultry is directed by the Automated Import Information System (AIIS), which stores results from all port-of-entry samples for each country and for each plant. All shipments are inspected for transportation damage, labeling, proper certification, general condition, and accurate count. AIIS assigns a variety of types of inspections, which may include analysis for chemical residues. Residue analyses are not limited to those compounds included in the domestic residue program. FSIS can initiate a special sampling plan when there is a need to monitor a country for residues of a specific compound, based on detection of violative residues at port of entry, or other information concerning risk to human health. Decisions about product acceptability are based on U.S. tolerances or action levels.

The first ten shipments of egg products from individual foreign establishments are subjected to 100 percent reinspection, to establish a history of compliance for each product category. This level is reduced to a random selection of one reinspection out of eight shipments, which continues as long as the product is in compliance. If a positive result is found in an egg product, import requests would be denied until foreign officials and FSIS determined that egg products originating from that country are safe for human consumption.

Shipments that are sampled during routine monitoring are eligible to be stamped with the U.S. mark of inspection and allowed to enter commerce prior to receipt of the results of the analysis. If violative results are subsequently reported, imported product bearing the U.S. mark of inspection cannot be used as human food; the importer does not have the option of recalling the product and exporting it from the U.S. It must either be destroyed or, if approved by FDA, converted to animal food. By contrast, if the importer chooses to voluntarily hold the shipment until the results are received, and the results are found to be violative, the shipment is refused entry as human food, and is either exported from the United States, destroyed or, if approved by FDA, allowed entry to the U.S. as animal food.

Section 3

The 2004 FSIS National Residue Program Design

The Food Safety and Inspection Service (FSIS) has focused special attention on the design of the monitoring plan for domestic products, and of the import residue plan for imported products, since these are the Agency's principal sources of information on the occurrence of residues in meat, poultry, and egg products. The remainder of this document will explain how FSIS designed the 2004 FSIS National Residue Program (NRP) Domestic Monitoring Plan, and Import Residue Plan, and will provide a complete listing of the residues and production classes that are sampled under these programs.

The first step in the design of these sampling plans is to generate a comprehensive list of residues of concern in meat, poultry and egg products. To accomplish this, FSIS coordinates annual meetings of the Surveillance Advisory Team (SAT), which is comprised of members from the Environmental Protection Agency (EPA), the Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), the Animal and Plant Health Inspection Service (APHIS), the Agricultural Marketing Service (AMS), the Agricultural Research Service (ARS), and FSIS. This interagency committee identifies the priority public health compounds of concern, and provides FSIS with detailed information about each compound. FSIS then combines this information with its historical data on compound violation rates to develop the domestic Monitoring Plan, and the Import Residue Plan. These sampling plans guide the allocation of FSIS laboratory and inspection resources.

Factors taken into consideration in developing the domestic Monitoring Plan, and the Import Residue Plan, are:

- The overall estimated relative public health concern associated with each compound or compound class in meat, poultry, and egg products;
- The production or product classes in which each compound or compound class is likely to be of concern;
- The availability of analytical methods, which determines which compounds or compound classes can be analyzed; and
- The analytical capacity of the FSIS laboratories, which determines how many analyses of each compound or compound class can be performed.

The final form of the scheduled sampling plans is determined by the estimated relative public health risk represented by each combination of residue and production class and by the availability of methods and resources to sample for these residues. FSIS attaches a high priority to obtaining new or improved methods for highly ranked residues.

The selection process used to design the Import Residue Plan is similar to that of the domestic plans, with two important exceptions. First, since many countries ship processed products only, it is often not possible to test raw product at the U.S. port-of-entry. Further, even when raw product is shipped, it often consists of muscle tissue only. By contrast, domestic residue testing often is targeted towards organ tissues (typically kidney and liver). This is because many residues concentrate in organs, which makes them easier to detect. Because of this concentration effect, FDA often bases its tolerances for veterinary drugs upon the levels found in kidney or liver. Second, while countries are required to identify the animal species used in each product, they are not required to identify the production class. Testing on imported meat and poultry is subdivided by animal species (e.g., chicken vs. pig), and cannot be further subdivided within a species (e.g., steer vs. heifer vs. dairy cow. vs. formula-fed veal). Egg products, however, can be distinguished as a separate category.

Because different countries have different approved compounds and different use practices, the compounds analyzed in the Import Residue Plan may not necessarily be the same as those in the Domestic Monitoring Plan.

SURVEILLANCE ADVISORY TEAM (SAT)

PURPOSE

The SAT participants identify:

- The "universe" of compounds,
- Specific residues of public health concern,
- Analytical residue method development needs
- Emerging issues for chemical hazards

CHAIR

- Director, Zoonotic Diseases and Residue Surveillance Division, Office of Public Health and Science (OPHS), FSIS, USDA

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- Office of Pesticides, Prevention, and Toxic Substances

HHS (Department of Health and Human Services)

- FDA, Center for Food Safety and Applied Nutrition
- FDA, Center for Veterinary Medicine
- Centers for Disease Control and Prevention

USDA

- Agricultural Marketing Service
- Agricultural Research Service
- Animal and Plant Health Inspection Service
- Food Safety and Inspection Service